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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/058,267	01/25/2002	David P. Hornby	P-693	4990

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EXAMINER	
SWITZER, JULIET CAROLINE	
ART UNIT	PAPER NUMBER
1634	

DATE MAILED: 05/19/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/058,267	HORNBY ET AL.	
	Examiner	Art Unit	
	Juliet C. Switzer	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-31* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *25 January 2002* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Priority

1. It is noted that this application appears to claim subject matter disclosed in prior Application No. 09/727138, filed 11/29/00. A reference to the prior application must be inserted as the first sentence of the specification of this application or in an application data sheet (37 CFR 1.76), if applicant intends to rely on the filing date of the prior application under 35 U.S.C. 119(e) or 120. See 37 CFR 1.78(a). For benefit claims under 35 U.S.C. 120, the reference must include the relationship (i.e., continuation, divisional, or continuation-in-part) of all nonprovisional applications. Also, the current status of all nonprovisional parent applications referenced should be included.

If the application is a utility or plant application filed under 35 U.S.C. 111(a) on or after November 29, 2000, the specific reference to the prior application must be submitted during the pendency of the application and within the later of four months from the actual filing date of the application or sixteen months from the filing date of the prior application. If the application is a utility or plant application which entered the national stage from an international application filed on or after November 29, 2000, after compliance with 35 U.S.C. 371, the specific reference must be submitted during the pendency of the application and within the later of four months from the date on which the national stage commenced under 35 U.S.C. 371(b) or (f) or sixteen months from the filing date of the prior application. See 37 CFR 1.78(a)(2)(ii) and (a)(5)(ii). This time period is not extendable and a failure to submit the reference required by 35 U.S.C. 119(e) and/or 120, where applicable, within this time period is considered a waiver of any benefit of such prior application(s) under 35 U.S.C. 119(e), 120, 121 and 365(c). A priority

claim filed after the required time period may be accepted if it is accompanied by a grantable petition to accept an unintentionally delayed claim for priority under 35 U.S.C. 119(e), 120, 121 and 365(c). The petition must be accompanied by (1) the reference required by 35 U.S.C. 120 or 119(e) and 37 CFR 1.78(a)(2) or (a)(5) to the prior application (unless previously submitted), (2) a surcharge under 37 CFR 1.17(t), and (3) a statement that the entire delay between the date the claim was due under 37 CFR 1.78(a)(2) or (a)(5) and the date the claim was filed was unintentional. The Director may require additional information where there is a question whether the delay was unintentional. The petition should be addressed to: Mail Stop Petition, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 5, 19, 20, 25, and 26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 5 is indefinite over the recitation "group consisting of methyl, ethyl, or hydrocarbon..." because the use of the word "or" is improper to recite the group is improper Markush language as it is unclear which members are actually part of the group. Amendment of the claim to recite "and" instead of "or" would obviate this concern.

Claims 19-20 are indefinite because they depend from claim 118, but there is no claim 118 in the application, and thus, it is unclear which claim the rejected claims are intended to be dependent upon.

In claim 25 there is insufficient antecedent basis for the recitation "said IP-RP-HPLC separation" because while the previous claim refers to IP-RP-HPLC, it does not refer to an IP-RP-HPLC separation.

In claim 26, there is insufficient basis for the recitation "said DNA" in line one of the claim. Neither claim 26 nor any of the claims from which claim 26 depends previously recite DNA.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1, 2, 3, 16, 23, and 24 are rejected under 35 U.S.C. 102(b) as being anticipated by Abel *et al.* (Journal of Chromatography, 1988, 446:187-189).

Abel *et al.* teach a method which comprises the steps of (a) contacting an RNA molecule with a cleavage reagent (in particular a purified ribonuclease) that is capable of partially hydrolyzing the RNA molecule; and (b) separating and detecting the cleaved RNA by IP-RP-HPLC (p. 188). The HPLC method used by Abel *et al.* is considered to be an IP-RP-HPLC

method because the method uses an ion pair (ammonium dihydrogenphosphate), a reverse phase stationary phase (octadecyl-silica 100 Polyol column) with HPLC.

In the methods taught by Abel *et al.*, the IP-RP-HPLC employs a separation medium that is silica coated with a hydrocarbon, namely octadecyl-silica (p. 188). This separation medium is thus a separation medium that is substantially free of multivalent cations that are capable of interfering with polynucleotide separations(p. 188). Furthermore, in the methods taught by Abel *et al.*, the cleavage reagent is a nuclease, specifically, a ribonuclease (RNase) (p. 188).

The methods taught by Sawyer *et al.* are considered to be Matched Ion Polynucleotide Chromatography because they use matched ions (i.e. the KH_2PO_4) to accomplish polynucleotide chromatography.

Thus, the method provided by Abel *et al.* meets the limitations of rejected claims 1, 2, 3, 16, 23, and 24.

6. Claims 1, 2, 3, 11, 15, and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by Sawyer *et al.* (Journal of Chromatography, 496 (1989) 450-455).

Sawyer *et al.* teach a method which comprises the steps of (a) contacting an RNA molecule with a cleavage reagent (in particular a sodium hydroxide) that is capable of partially hydrolyzing the RNA molecule; and (b) separating and detecting the cleaved RNA by IP-RP-HPLC (p. 452). The HPLC method used by Sawyer *et al.* is considered to be an IP-RP-HPLC method because the method uses an ion pair (ammonium dihydrogenphosphate), a reverse phase stationary phase (in particular the Resolve C_{18} particles) with HPLC.

In the methods taught by Sawyer *et al.*, the IP-RP-HPLC employs a separation medium that is silica coated with a hydrocarbon, namely the Resolve C_{18} particles. This separation

medium is thus a separation medium that is substantially free of multivalent cations that are capable of interfering with polynucleotide separations. The mobile phase used by Sawyer *et al.* further comprises a counterion agent that is a quaternary ammonium salt (tetrabutyl ammonium hydrogensulfate), and the counterion agent is sulfate.

The methods taught by Sawyer *et al.* are considered to be Matched Ion Polynucleotide Chromatography because they use matched ions (i.e. the tetrabutyl ammonium hydrogen sulfate and the KH_2PO_4) to accomplish polynucleotide chromatography.

Thus, the method provided by Sawyer *et al.* meets the limitations of rejected claims 1, 2, 3, 11, 15, and 16.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. Claims 1, 2, 4, 5, 7, 9, 10, 11, 12, 14, 15, 17, 21, 22, 23, 24, 25, 26, 27, 28, 29 and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hampel *et al.* (Biochemistry, 1998, 37, 14672-14682) in view of Gjerde *et al.* (WO 9848913) and further in view of Chenchik *et al.* (WO 9935289).

Hampel *et al.* teach a method for analyzing the structural properties of an RNA molecule comprising:

(a) contacting said RNA molecule with a cleavage reagent which effects partial hydrolysis of said RNA molecule, wherein said partial hydrolysis is attenuated in a region of said RNA molecule that is relatively inaccessible to solvent (p. 14674);

(b) separating and detecting the cleaved RNA, wherein the absence of cleavage events in a region of the RNA indicates that said region is relatively inaccessible to solvent (p. 14674);

In Hampel *et al.*'s method, the RNA is detectably labeled (p. 14674). Hampel *et al.* use a hydroxyl radical generated using $Fe(EDTA)^{2-}$ as a cleavage reagent (p. 14674), and they also use a nuclease that is an RNase as a cleavage reagent (p. 14675, Figure 2 legend). The cleavage reactions that utilize T1 ribonuclease digest and alkali hydrolysis ladders are RNA sequencing reactions, and this reaction is used as a parallel reaction for the purposes of comparison of the chromatography patterns (i.e. to "phase" the reaction) (p. 14675, Figure 2 legend). Hampel *et al.* teach that the regions of protection indicate a solvent-inaccessible core within the tertiary structure of the ribozyme complex (ABSTRACT). Hampel *et al.* tech that the tertiary structure of the RNA molecule and the two domains is relatively inaccessible to solvent due to intermolecular and intramolecular interactions (pages 14676-80, figures 4-9). Hampel *et al.* use

their methodology to characterize the three dimensional structure of the RNA molecule (at least pages 14675-14676).

Hampel *et al.* do not teach methods in which the cleaved RNA is separated by IP-RP-HPLC, or Matched Ion Polynucleotide Chromatography in particular.

Gjerde *et al.* teach a method for separating a mixture of polynucleotides by using Matched Ion Polynucleotide Chromatography (MIPC) (pages 2-3). Gjerde *et al.* specifically disclose that their method can be used in the separation of RNA (p. 10, line 4), and teach that their invention should most preferably be carried out within the temperature range of 50°C to 75°C and that in general, separation of single stranded fragments should be performed at higher temperature (page 17, lines 15-17). Gjerde *et al.* teach that MIPC employs a separation medium that is substantially free of multivalent cations that are capable of interfering with polynucleotide separations (page 3). Gjerde *et al.* teach that the separation method comprises polymer beads having an average diameter of 0.5 to 100 microns (page 3, line 2), and that said beads can be unsubstituted or substituted with a moiety selected from the group consisting of methyl, ethyl, and hydrocarbon, wherein the hydrocarbon has from 23 to 1000000 carbons (page 3). Gjerde *et al.* teach that the beads are acid washed to remove any residual metal contaminants (p. 3, lines 20-21). Gjerde *et al.* teach that the MIPC employs a mobile phase using acetonitrile as a solvent (p. 17, line 25). Gjerde *et al.* teach that the MIPC employs triethylammonium acetate as a counterion agent (p. 17, lines 10-11).

Chenchik *et al.* exemplify the use of denaturing MIPC for the size separation of RNA molecules, specifically using the Transgenomics WAVE HPLC System (p. 22, section A.2),

which applicant has indicated as a preferred system for performing MIPC (see instant specification, page 16).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to have used the separation methods taught by Gjerde *et al.*, and exemplified by Chenchik *et al.*, in the RNA analysis methods taught by Hampel *et al.* The ordinary practitioner would have been motivated to use the MIPC methods taught by Gjerde *et al.* in place of the electrophoresis methods taught by Hampel *et al.* because Gjerde *et al.* specifically teach that their methods are useful for separating samples containing mixtures that are the result of cleavage of RNA with restriction endonucleases or other enzymes or chemicals (page 16, lines 18-20), and the methods taught by Hampel *et al.* require the separation of cleaved RNA, and Gjerde *et al.* teach that although electrophoresis is the traditional method used to separate polynucleotides, "liquid chromatographic separations of polynucleotides are becoming more important because of the ability to automate the analysis and to collect fractions after they have been separated." Furthermore, the ordinary practitioner would have been motivated by the success of Chenchik *et al.*, who exemplify the separation of RNA molecules using MIPC, to apply this method to the cleaved RNA molecules taught by Hampel *et al.*

10. Claims 3, 6, and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hampel *et al.* (Biochemistry, 1998, 37, 14672-14682) in view of Gjerde *et al.* (WO 9848913) and further in view of Chenchik *et al.* (WO 9935289) as applied to claim1, 2, 4, 5, 7, 9, 10, 11, 12, 13, 14, 15, 17, 21, 22, 23, 23, 24, 26, 27, 28, 29, 30, 32, and 33 above, and further in view of Gjerde *et al.* (US 5972222).

The teachings of Hampel *et al.* (Biochemistry, 1998, 37, 14672-14682) in view of Gjerde *et al.* (WO 9848913) and further in view of Chenchik *et al.* (WO 9935289) are applied to claims 3, 6, and 8 as they are applied in the preceding rejection. Hampel *et al.*, Gjerde *et al.* (WO, '98), and Chenchik *et al.* do not teach MIPC methods which utilize any of the particles recited in claim 3, a monolith, or wherein the separation medium has been subjected to treatment with a multivalent cation binding agent.

Each of these limitations, however, were known to be utilized in MIPC methods at the time the invention was made. Gjerde *et al.* teach that MIPC should be carried out using non-polar wide pore separation media, and that such media include silica, zirconia, and alumina (Col. 5, lines 56-67). Gjerde *et al.* further teach that the separation can also be a monolith column (Col. 6, lines 4-5). Gjerde *et al.* teach that to ensure that the separation media are free of multivalent cation contaminants, the separation medial can be washed with EDTA or other chelating agents (Col. 6, lines 31-33).

Thus, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to have included any of the separation media or media treatments taught by Gjerde *et al.* (US 5972222) in the method that is taught by Hampel *et al.* Gjerde *et al.* (WO), and Chenchik *et al.* The ordinary practitioner would have been motivate to make such an inclusion because Gjerde *et al.* (US) are specifically teaching methods that can be used in the MIPC methodology discussed by Gjerde *et al.* (WO), and the ordinary practitioner would have been motivated to use these in order to provide alternative methods for practicing the methods disclosed in Gjerde *et al.* (WO).

11. Claims 6 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hampel *et al.* (Biochemistry, 1998, 37, 14672-14682) in view of Gjerde *et al.* (WO 9848913) and further in view of Chenchik *et al.* (WO 9935289) as applied to claims 1, 2, 4, 5, 7, 9, 10, 11, 12, 13, 14, 15, 17, 21, 22, 23, 23, 24, 26, 27, 28, 29, 30, 32, and 33 above, and further in view of Hatch (US 6238565).

The teachings of Hampel *et al.* (Biochemistry, 1998, 37, 14672-14682) in view of Gjerde *et al.* (WO 9848913) and further in view of Chenchik *et al.* (WO 9935289) are applied to claims 3, 6, and 8 as they are applied in the preceeding rejection. Hampel *et al.*, Gjerde *et al.* (WO, '98), and Chenchik *et al.* do not teach MIPC methods which utilize a monolith or wherein the counterion agent is tetrabutylammonium acetate.

Hatch provides monolithic columns for use in ion-pair reverse-phase chromotagraphy, and teach that "the monolithic columns of the present invention provide all of the advantages of the previous best technology for polynucleotide separations..., without the need to tediously prepare beads and pack them into efficient columns (Col. 4, lines 15-19)." Hatch *et al.* further teach that tetrabutylammonium acetate is an effective ion-paring agent in both methacrylate and styrene-based columns (Col. 8, lines 44-46).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to have combined the methods of Hatch with those taught by Hampel *et al.* in view of Gjerde *et al.* in view of Chenchik *et al.* in order to take advantage of the monolithic columns taught by Hatch *et al.*

12. Claims 18, 19, and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hampel *et al.* (Biochemistry, 1998, 37, 14672-14682) in view of Gjerde *et al.* (WO 9848913)

and further in view of Chenchik *et al.* (WO 9935289) as applied to claim1, 2, 4, 5, 7, 9, 10, 11, 12, 13, 14, 15, 17, 21, 22, 23, 23, 24, 26, 27, 28, 29, 30, 32, and 33 above, and further in view of Chan *et al.* (Analytical Biochemistry 242, 214-220 (1996)).

The teachings of Hampel *et al.* (Biochemistry, 1998, 37, 14672-14682) in view of Gjerde *et al.* (WO 9848913) and further in view of Chenchik *et al.* (WO 9935289) are applied to claims 3, 6, and 8 as they are applied in the preceding rejection. Hampel *et al.*, Gjerde *et al.* (WO, '98), and Chenchik *et al.* do not teach MIPC methods which utilize in which the RNA molecule is detectably labeled with a fluorescent label, particularly with FAM.

Chan *et al.* teach RNase protection assays which utilize fluorescein labeled UTP's (p. 215). The fluorescein labeled 12-UTP was purchased from Boehringer Mannheim, and the flurocscein molecule attached to the dUTP is 5-carboxyfluorescein, also known as FAM. The Bochringer Mannheim catalog information page is attached to the Chan *et al.* reference solely for the purpose of confirming that the fluorescein used by Chan *et al.* is in fact FAM.

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to have used the FAM label used by Chan *et al.* in the methods provided by Hampel *et al.* in view of Gjerde *et al.* and Chenchik *et al.* because this fluorescent label is routinely used in nucleic acid assays, Chan *et al.* demonstrate its use in protection assays, and the substitution of a flurophore for a radiolabel (as was used by Hampel *et al.*) would have the benefit of providing a method that functions without the use of radioactivity.

13. Claims 31 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hampel *et al.* (Biochemistry, 1998, 37, 14672-14682) in view of Gjerde *et al.* (WO 9848913) and further in view of Chenchik *et al.* (WO 9935289) as applied to claim1, 2, 4, 5, 7, 9, 10, 11, 12, 13, 14, 15,

17, 21, 22, 23, 23, 24, 26, 27, 28, 29, 30, 32, and 33 above, and further in view of Weeks *et al.* (Cell, Vol. 82, 221-230, 1995).

The teachings of Hampel *et al.* (Biochemistry, 1998, 37, 14672-14682) in view of Gjerde *et al.* (WO 9848913) and further in view of Chenchik *et al.* (WO 9935289) are applied to claims 3, 6, and 8 as they are applied in the preceding rejection. Hampel *et al.*, Gjerde *et al.* (WO, '98), and Chenchik *et al.* do not teach methods wherein the intermolecular interaction is between the RNA molecule and an RNA-binding protein.

Weeks *et al.* exemplify the use of a an RNA cleavage reaction for analyzing the structural properties of an RNA molecule wherein the RNA molecule includes a region that is relatively inaccessible to solvent owing to intermolecular interactions and wherein the intermolecular interaction is between said RNA molecule and an RNA-binding protein (p. 222).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to have used the method provided by Hampel *et al.* in view of Gjerde *et al.*, and further in view of Chenchik *et al.* to assay the structural properties of the RNA taught by Weeks *et al.* in order to have taken advantages of the benefits of the MIPC methodology provided by Gjerde *et al.* for the study of a protein-RNA system that exemplifies features fundamental to ribonucleoprotein enzymes.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Juliet C. Switzer whose telephone number is 703 306 5824. The examiner can normally be reached on Monday through Friday, from 9:00 AM until 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones can be reached on 703 308 1152. The fax phone numbers for the

organization where this application or proceeding is assigned are 703 305 3592 and (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 308 0196.

JEFFREY FREDMAN
PRIMARY EXAMINER

Juliet C. Switzer
Patent Examiner
AU 1634

May 15, 2003